IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

Kathryn Kiker, et al., Plaintiffs, vs. SmithKline Beecham Corporation d/b/a GlaxoSmithKline LLC, Defendant.	:	Case No. 2:14-cv-02164-EAS-TPK Chief Judge Edmund A. Sargus, Jr. Magistrate Judge Terence P. Kemp

DEFENDANT GLAXOSMITHKLINE LLC'S MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OF OTHER CLAIMS, LAWSUITS, GOVERNMENTAL INVESTIGATIONS OR CHARGES, AND MEDIA REPORTS
(ORAL ARGUMENT REQUESTED)

Defendant GlaxoSmithKline LLC ("GSK") submits its Motion *in Limine* to Exclude Evidence of other Claims, Lawsuits, Governmental Investigations or Charges, and Media Reports because such evidence is irrelevant and unfairly prejudicial, and in certain examples, hearsay, and therefore inadmissible.

I. INTRODUCTION

GSK seeks to preclude Plaintiffs and their experts from presenting any evidence of or reference to other claims, lawsuits, governmental investigations or charges,[1] and media reports regarding Paxil® or Paxil CR® (collectively "Paxil"), other selective serotonin reuptake inhibitors, or other medications manufactured or sold by GSK. GSK anticipates that Plaintiffs will seek to introduce such evidence in an attempt to show that Paxil has caused other birth

[1] GSK does not seek to exclude the U.S. Food and Drug Administration's regulation and actions concerning the labeling of Paxil, or analysis concerning use of Paxil during pregnancy except as otherwise set forth in its motions *in limine*. Separately, GSK has filed its Motion *in Limine* to Exclude Evidence of its 2012 Plea Agreement, Civil Settlement Agreements, and Associated Documents and will not address the issues of that Motion in this filing.

defects and that this somehow proves that Paxil caused C.S.'s heart defect (a ventricular septal defect, or "VSD") or that GSK allegedly acted improperly in unrelated circumstances and this somehow proves GSK acted improperly here.

There is no basis for admitting any of this purported "evidence." In all of the trials of Paxil pregnancy cases in the Philadelphia Mass Tort Program ("MTP"), the trial courts largely excluded this type of evidence. (*See Rader v. GSK*, Mar. 11, 2016 Order granting GSK's similar motion *in limine* (attached as Ex. 1)[2,3]; *Adams v. GSK*, Hearing Tr., June 26, 2012 a.m. session at 58:17-73:19 (granting GSK's similar motion *in limine*) (attached as Ex. 2); *Blyth v. GSK*, Nov. 9, 2010 Order (deferring ruling on GSK's similar motion *in limine*, Control No. 10030224, by agreement of the parties) (attached as Ex. 3)[4]; *Kilker v. GSK*, Trial Tr., Sept. 16, 2009 a.m. session at 15:25-17:21, 27:14-19 (denying plaintiffs' request to admit documents or make reference to governmental investigations) (relevant excerpts attached as Ex. 4).) This Court should follow suit for three reasons.

First, evidence of, or reference to, other claims, lawsuits, governmental investigations or charges, or media reports is not relevant. The issue here is whether Paxil caused C.S.'s VSD. The investigations or charges that Plaintiffs may reference did not involve any issues that bear on whether Paxil causes VSDs (or any other birth defect) or the labeling for Paxil and use in pregnancy. There also is no evidence that the events referenced in the investigations or charges influenced Kathryn Kiker's prescribing physician. Similarly, whether there have been other lawsuits filed against GSK or other companies is irrelevant to whether Paxil caused C.S.'s VSD.

[2] For the convenience of the Court, exhibits are attached to the Declaration of William D. Kloss, Jr., accompanying this Motion.
[3] The order in *Rader v. GSK* also excluded evidence of GSK's 2012 Plea Agreement and Civil Settlement Agreements. GSK is filing herewith a separate motion *in limine* to exclude such evidence. *See* GSK's Motion *in Limine* to Exclude Evidence of its 2012 Plea Agreement, Civil Settlement Agreements, and Associated Documents.
[4] Plaintiffs never offered the evidence at issue in the trial of *Blyth v. GSK*.

Second, even if Plaintiffs can somehow establish the relevance of these unrelated issues — which they cannot — any probative value is strongly outweighed by the danger of unfair prejudice to GSK, undue delay, and confusion of issues for the jury.

Third, even if evidence such as media reports, other claims, or unrelated investigations were not unfairly prejudicial, they would still be inadmissible hearsay.

II. ARGUMENT

A. Evidence of, or Reference to, Other Claims, Lawsuits, Governmental Investigations or Charges, and Media Reports is Not Relevant.

Before Plaintiffs can introduce evidence of other claims, lawsuits, governmental investigations or charges, or media reports, they must show that the circumstances involved are "substantially similar" to those in this case. *See Buck v. Ford Motor Co.*, 526 F. App'x 603, 606-07 (6th Cir. 2013) (affirming exclusion of evidence of other accidents where the plaintiff did not show that they were substantially similar); *Holbrook v. Dorel Juvenile Grp.*, 2016 WL 927230, at *2 (S.D. Ohio Mar. 7, 2016) (granting motion *in limine* to exclude evidence of other accidents where the plaintiff did not show that they were substantially similar).

The substantial similarity requirement is based in sound logic, because the circumstances surrounding other claims, lawsuits, investigations or charges, or media reports raise highly individualized questions. For example, questions that would need to be answered – and litigated in mini-trials – before the Court could determine if the Paxil experiences of other individuals are "substantially similar" to Kathryn Kiker's Paxil use and C.S.'s alleged Paxil exposure include: (1) What was the patient's age and medical history? (2) What was the patient's state of mental health before and during her Paxil usage? (3) Did the patient receive Paxil via a prescription? (4) If through a prescription, was the medication appropriately prescribed? (5) What did the physician tell the individual about the risks associated with Paxil? (6) What dosage of Paxil did

the patient take and for how long? (7) What were the patient's reasons for seeking treatment? (8) Did the patient take other medications or undergo treatment while taking Paxil? (9) When did the patient allegedly take Paxil? (10) Did the individual use illegal drugs or alcohol while using Paxil? (11) Was the individual exposed to recognized teratogens? (12) Did the individual have any conditions that might have affected how the drug worked? (13) Was there any family history of the condition? (14) Was there any connection between the individual's use of Paxil and any GSK conduct? (15) When during the individual's pregnancy did she take Paxil? and (16) What precise congenital abnormalities were present? Absent such an analysis, evidence of other claims or lawsuits would only show that other individuals also claim to have been injured by Paxil. *See, e.g.*, *In re Paxil Litig.*, 218 F.R.D. 242, 245 (C.D. Cal. 2003) (reasoning that although plaintiffs "have all consumed Paxil . . . the similarities end there").

Similarly, references to media reports about Paxil or other medications would show only that the media has reported on Paxil or other medications, just as references to investigations or charges would show only that an agency has investigated Paxil or other medications. None of this constitutes the causation evidence that Plaintiffs need to support their claim that Paxil caused C.S.'s VSD or that, even if it did, GSK should be liable.

In sum, any reference to the materials Plaintiffs may wish to introduce would be irrelevant because the materials do not meet the substantial similarity requirement.

B. Any Probative Value is Outweighed by the Prejudice of Introducing These Materials.

Even if Plaintiffs could establish the "substantial similarity" of other claims, lawsuits, governmental investigations or charges, or media reports – which they cannot – exclusion is proper because the probative value of this evidence is heavily outweighed by the danger of unfair prejudice to GSK and confusion of the issues for the jury. FED. R. EVID. 403.

Admission of this evidence would inflame and mislead the jury, thereby unduly prejudicing GSK. *See, e.g.*, *McLeod v. Parson Corp.*, 73 F. App'x 846, 854 (6th Cir. 2003) (affirming exclusion of evidence of other lawsuits that had "no clear nexus" to the case; reasoning that the potential for prejudice "would have substantially outweighed [the] probative value, and this evidence would have misled the jury"). Specifically, presentation of other claims evidence will prejudice GSK by instilling in the jury the incorrect impression that Paxil use during pregnancy routinely causes congenital heart defects. *See, e.g.*, *Ross v. Am. Red Cross*, 2012 WL 2004810, at *5 (S.D. Ohio June 5, 2012) (allegations "in other cases and under different circumstances, are of minimal probative value" and "[t]his value is outweighed by the risk that the jury will draw improper conclusions from other incidents in which the Red Cross's actions allegedly caused injuries"). Additionally, evidence of irrelevant claims and reports would confuse the jury and distract the jury's focus from the central issue in this case, *i.e.*, whether Paxil caused C.S.'s VSD. *See, e.g.*, *Geiger v. Pfizer*, Inc., 2009 WL 1026479, at *11 (S.D. Ohio April 15, 2009) (even if evidence of other lawsuits is marginally relevant, "the probative value of this evidence is substantially outweighed by the danger of unfair prejudice and would likely cause confusion").

A primary concern with presentation of these materials is that Plaintiffs will need to spend significant time presenting evidence about another individual's claims. GSK would then need to present evidence and testimony rebutting Plaintiffs' claim that Paxil caused a non-party's birth defect. Discussion of these issues will (1) occupy this Court's valuable time; and (2) result in a trial-within-a-trial on irrelevant and collateral issues. *See Am. Red Cross*, 2012 WL 2004810, at *5 (evidence of other cases "may also invite mini-trials about facts and circumstances that may not be similar to the present case").

Additional prejudice will occur if government investigations or charges are introduced at trial, because jurors may perceive them to possess "an aura of special reliability and trustworthiness which would not have been commensurate with [their] actual reliability." *City of New York v. Pullman, Inc.*, 662 F.2d 910, 915 (2d Cir. 1981) (internal quotation omitted) (affirming exclusion of government report that was prepared "for very different purposes tha[n] those for which it was offered at trial" and whose admission would "protract an already prolonged trial with an inquiry into collateral issues regarding the accuracy of the report and the methods used in its compilation"); *see also, e.g.*, *Denny v. Hutchinson Sales Corp.*, 649 F.2d 816, 822 (10th Cir. 1981) (noting "there is a real possibility that the jury would give undue deference to" a report from the Colorado Civil Rights Commission).

Accordingly, the Court should exclude references to other claims, lawsuits, governmental investigations or charges, or media reports because any minimal probative value they may possess is outweighed by the likelihood they would mislead the jury and unduly prejudice GSK.

C. Evidence of Other Claims, Lawsuits, Governmental Investigations or Charges, and Media Reports Constitutes Inadmissible Hearsay.

Plaintiffs will likely seek to introduce evidence of other claims, lawsuits, investigations or charges, and media reports to suggest that Paxil has caused other birth defects or that GSK did not act appropriately – that is, for the "truth of the matter asserted." This is hearsay. FED. R. EVID. 801.

Hearsay evidence is generally inadmissible, and these references — unsubstantiated, unreliable, and unverifiable — are precisely the kind of evidence that the hearsay rule targets for exclusion. *See O'Neal v. Burt*, 582 F. App'x 566, 574 (6th Cir. 2014) (government report containing unverified statements is "rank hearsay" and inadmissible). Moreover, media reports — in print, on air, or otherwise transmitted — offered for the truth of the matter asserted are

inadmissible hearsay. *See Turner v. City of Taylor*, 412 F.3d 629, 652 (6th Cir. 2005) (newspaper article inadmissible hearsay); *Williams v. United Dairy, Inc.*, 2005 WL 1077596, at *5 (S.D. Ohio Apr. 18, 2005) (video news report inadmissible hearsay).

In fact, such evidence likely would include multiple layers of hearsay and is not admissible unless each level of hearsay meets an exception. FED. R. EVID. 805. These layers of hearsay include allegations or statements made by many third-party sources who cannot be cross-examined without having the sources themselves testify.

D. Evidence Regarding a Congressional Investigation, a Pediatric Patient Lawsuit, or a FDA Investigation About a Paxil CR Manufacturing Facility is Irrelevant, Confusing, and Highly Prejudicial.

Based on their Exhibit List and deposition designations, Plaintiffs appear to focus on three irrelevant issues: (1) a Congressional investigation involving third-party physicians not before the Court; (2) a consumer fraud lawsuit filed by the former New York Attorney General regarding pediatric use of Paxil; and (3) settlement agreements concerning manufacturing at GSK's former facility in Cidra, Puerto Rico. None is remotely relevant, much less admissible, at the trial of this case.[5,6]

1. The Grassley Investigation

Congressional inquiries, including an investigation by U.S. Senator Charles Grassley, have suggested that some third-party physicians who may have made presentations to other physicians regarding Paxil or other drugs may not have properly disclosed their financial

[5] *See, e.g.*, Plfs' Exhibit List (Doc. 159) at 57-58 (listing documents related to the Congressional investigation as Exhibit Nos. 1415-1427); *id*. at 139 (listing documents related to the Cidra settlement as Exhibit Nos. 4813-4816 and 4822-4823, 4826-4827); Plfs' Deposition Designations (Doc. 158) at 23-30 (designating the testimony of Mr. Collier, who gave a deposition in *Orrick v. GSK* about the marketing at issue in the New York lawsuit).

[6] Plaintiffs also plan to put at issue federal governmental investigations and *qui tam* lawsuits relating to multiple medications manufactured or sold by GSK, and the 2012 Plea Agreement and Civil Settlement Agreements GSK entered to resolve these investigations and lawsuits. *See* Plfs' Exhibit List (Doc. 159) at 138-139, 141-142 (listing documents related to GSK's 2012 Plea Agreement as Exhibits 4804-4812, 4817-4821, 4828, 4885-4894, 4915, 4926, 4928-4929, 4931-4939). As set forth above, GSK has filed a separate motion *in limine* to exclude this evidence.

relationships to the academic institutions that employed them. At the first Paxil Pregnancy trial, the court denied the plaintiffs' request to admit documents or make reference to information related to Senator Grassley's investigation. (*See* Ex. 4, *Kilker* Trial Tr. at 16:4-17:21, 27:14-19.)

It would be improper for Plaintiffs to reference these investigations for the same reasons: (1) the investigation involved third-party physicians, not any wrongdoing by GSK; and (2) there is no evidence that any of Plaintiffs' physicians were influenced by – or even knew of – the physicians who were the subjects of these investigations. The Court should also exclude Senator Grassley's inquiry because it was not completed, and unfinished investigations are unreliable and potentially misleading. *See, e.g.*, *Toole v. McClintock*, 999 F.2d 1430, 1431 (11th Cir. 1993) (reversing verdict for plaintiffs because court erred by admitting government report about defendant's product that was not final and only made proposed findings). Plaintiffs' only use for this evidence would be to suggest GSK's "guilt by association." This evidence is irrelevant because it is not probative of any action, behavior, or statement attributable to GSK.

2. The Spitzer Lawsuit

GSK entered a Consent Order with then-New York Attorney General ("NYAG") Eliot Spitzer that resolved a lawsuit in which the NYAG alleged that "GSK failed to disclose the results of certain clinical studies of Paxil (paroxetine HCl) in adolescent and pediatric patients, and that GSK was under a duty under New York law to disclose those results." (Aug. 26, 2004 Consent Order & Judgment ("Consent Order") at ¶ 3 (attached as Ex. 5).) The NYAG's lawsuit against GSK solely concerned the use of Paxil in children and adolescents. (*See New York v. GSK* Compl. at 1-3 (attached as Ex. 6).)

There is no question that the NYAG suit had nothing to do with the use of Paxil during pregnancy, heart defects or birth defects allegedly caused by Paxil. Evidence concerning this

Consent Order is irrelevant to Plaintiffs' claims that Paxil caused C.S.'s VSD. Not only are the allegations in the NYAG lawsuit irrelevant, GSK ***did not admit any liability*** in entering the Consent Order. (*See* Ex. 5, Consent Order ¶ 1 ("By consenting to the entry of this Consent Order & Judgment, neither GSK nor SKB admits any of the acts alleged in the complaint filed by the Attorney General in the Supreme Court for the County of New York on or about June 2, 2004.").)

The Court should also exclude any evidence of or reference to the Consent Order because it provides that it "***shall not be admissible in any other case for any purpose***." (*Id*. ¶ 10 (emphasis added).) This provision comports with Federal Rule of Evidence 408, which bars evidence regarding compromise offers and negotiations to prove liability.

3. The Cidra Settlement

Plaintiffs may attempt to introduce documents relating to "the manufacture and distribution of certain adulterated drugs [Kytril, Bactroban, Paxil CR and Avandamet] made at GSK's now-closed Cidra, Puerto Rico, manufacturing facility . . . ." (*See* Oct. 26, 2010 U.S. DOJ Press Release (attached as Ex. 7).) Paxil CR is a controlled-release formulation of Paxil. The allegations related to Paxil CR were that the manufacturing process caused some Paxil CR two-layer tablets to split. (*See* Government Information (attached as Ex. 8), plea agreement (attached as Ex. 9), and civil settlement agreement (attached as Ex. 10).)

As part of its claims, the United States contended "that GSK sold certain batches, lots or portions of lots of drugs, the strength of which differed materially from, or the purity or quality of which fell materially below, the strength, purity or quality specified in the drugs' FDA applications or related documents . . . and caused false claims to be submitted to government

health care programs for certain quantities of adulterated Kytril, Bactroban, Paxil CR and Avandamet." (Ex. 7, DOJ Press Release.) The issues at Cidra have nothing to do with this case:

- The agreements relate only to GSK medications that Kathryn Kiker does not even allege that she took.
- During her pregnancy with C.S., Kathryn Kiker was prescribed Paxil, not Paxil CR. GSK did not distribute Paxil CR until 2002, a year after C.S. was born. There is no evidence that Kathryn Kiker ever ingested Paxil CR, let alone a split Paxil CR tablet.
- The plea agreement relates to Paxil CR lots released ***between February 20, 2004 and September 15, 2004 — three years*** after C.S. was born. (*See* Ex. 8, Information ¶ 59). This time period is not relevant to this case.
- The agreements pertain only to the manufacturing process for Paxil CR. Plaintiffs make no allegation concerning a manufacturing defect for Paxil CR (or Paxil).
- The agreements do not involve any contention that the Paxil CR manufacturing issues have anything to do with claims that Paxil can cause birth defects.

Plaintiffs have no argument connecting the Cidra agreements to their claims. As the court in *Adams v. GSK* stated in rejecting the argument that evidence regarding the Cidra plea would be admissible in a Paxil pregnancy trial: ***"We're not getting into guilty pleas. That's totally inadmissible and irrelevant."*** (Ex. 2, *Adams v. GSK*, June 26, 2012 Mot. Hr'g Tr., June 26, 2012 a.m. session at 62:21-64:9 (emphasis added).) Introduction of this evidence would be highly prejudicial to GSK, and the Court should exclude such evidence.

III. CONCLUSION

Based on the foregoing, GSK respectfully requests that this Court grant its Motion *in Limine* and enter an order excluding from trial any evidence of, or reference to, other claims, lawsuits, governmental investigations or charges, and media reports regarding Paxil, other SSRIs, and other medications manufactured or sold by GSK.

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CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing was served upon all counsel of record, this 24th day of January, 2017, by the Court's electronic service.

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ORDER

AND NOW, this __ day of _____, 2017, upon consideration of Defendant GlaxoSmithKline LLC's ("GSK") Motion *in Limine* to Exclude Evidence of Other Claims, Lawsuits, Governmental Investigations or Charges, and Media Reports, and any response thereto, and having considered the arguments of counsel, it is hereby ORDERED that Defendant's Motion is GRANTED:

(1) Plaintiffs, their counsel, and their witnesses are prohibited from mentioning or bringing before the jury, either directly or indirectly, upon voir dire, opening statement, interrogation of witnesses, argument, objections before the jury or by any other means, or in any other manner, any evidence of or reference to other claims or lawsuits, governmental investigations or charges, and media reports involving Paxil® or Paxil CR® (collectively "Paxil"), other SSRIs, or other medications manufactured or sold by GSK;

(2) Plaintiffs' counsel are instructed to inform Plaintiffs and all witnesses called by Plaintiffs not to volunteer, interject, disclose, state, mention in the presence of the jury or in any other way refer to any other claims or lawsuits, governmental investigations or charges, or media reports involving Paxil, other SSRIs, or other medications manufactured or sold by GSK; and

(3) Plaintiffs and their counsel are instructed that a violation of any of the Court's instructions in connection with this Motion would constitute undue harm to GSK's case and would deprive GSK of a fair and impartial trial, and that such violation and failure to abide by this Court's Order may bring about a mistrial and other appropriate relief, including, but not limited to, sanctions.

_____
Date

_____
Edumund A. Sargus, Jr.
Chief United States District Judge